

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)



REC'D 27 JAN 2006

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| Applicant's or agent's file reference JL-23656-PCT | FOR FURTHER ACTION | | See Form PCT/IPEA/416 |
| International application No. PCT/KR2004/003179 | International filing date(day/month/year) 04 DECEMBER 2004 (04.12.2004) | Priority date (day/month/year) 04 DECEMBER 2003 (04.12.2003) | |
| International Patent Classification (IPC) or national classification and IPC C07K 14/565(2006.01)i | | | |
| Applicant CJ CORPORATION et al | | | |

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
- a. ☐ (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:
- ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
- ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
- b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:
- ☒ Box No. I Basis of the report
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

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| Date of submission of the demand 30 JUNE 2005 (30.06.2005) | Date of completion of this report 13 JANUARY 2006 (13.01.2006) |
| Name and mailing address of the IPEA/KR  Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140 | Authorized officer PARK, JEONG UNG Telephone No. 82-42-481-8159  |

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/KR2004/003179

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☒ This report is based on translations from the original language into the following language English, which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3 and 23.1(b))
 - ☒ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
 - ☒ the international application as originally filed/furnished

 - ☐ the description:
 - pages _____ as originally filed/furnished
 - pages* _____ received by this Authority on _____
 - pages* _____ received by this Authority on _____

 - ☐ the claims:
 - pages _____ as originally filed/furnished
 - pages* _____ as amended (together with any statement) under Article 19
 - pages* _____ received by this Authority on _____
 - pages* _____ received by this Authority on _____

 - ☐ the drawings:
 - pages _____ as originally filed/furnished
 - pages* _____ received by this Authority on _____
 - pages* _____ received by this Authority on _____

 - ☐ the sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:
 - ☐ the description, pages _____
 - ☐ the claims, Nos. _____
 - ☐ the drawings, sheets _____
 - ☐ the sequence listing (*specify*): _____
 - ☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
 - ☐ the description, pages _____
 - ☐ the claims, Nos. _____
 - ☐ the drawings, sheets _____
 - ☐ the sequence listing (*specify*): _____
 - ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/KR2004/003179

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

| | | | |
|-------------------------------|--------|-----|-----|
| Novelty (N) | Claims | 1-5 | YES |
| | Claims | | NO |
| Inventive step (IS) | Claims | | YES |
| | Claims | 1-5 | NO |
| Industrial applicability (IA) | Claims | 1-5 | YES |
| | Claims | | NO |

2. Citations and explanations (Rule 70.7)

The present invention relates a method for the purification of human interferon beta (INF-beta) consisting of effective washing stage in which 40-60% propylene glycol is used.

The following documents have been considered for the purpose of the report:

D1: US 5244655 (Sep 14, 1993)

D2: US 4483849 (Nov 20, 1984)

1. Novelty

D1 describes a method for purifying of human INF-beta by RP-HPLC. D2 disclose a process for stabilizing purified human INF using propylene glycol, and the use of Affi-Gel Blue in column of affinity chromatography stage. The select use of 40-60% propylene glycol in washing stage is not disclosed in any of the prior art. Therefore, the subject-matter of claims 1-5 is considered to be novel under PCT Article 33(2).

2. Inventive Step

The present invention especially provides a purifying process of human INF-beta containing washing stage by 40-60% propylene glycol. D1 and D2 disclose the purifying process consisting of special techniques: Affi-Gel Blue in column of affinity chromatography stage, RP-HPLC and propylene glycol. The present invention shows a difference in the select use of propylene glycol in washing stage. However, the present invention claimed in claims 1-5 is considered to be easily invented by a person skilled in the art with knowledge of the prior art documents D1 and D2, without the exercise of inventive skill. Therefore, the subject-matter of claims 1-5 is not considered to involve an inventive step under PCT Article 33(3).

3. Industrial Applicability

The subject-matter of claims 1-5 is considered to be industrially applicable under PCT Article 33(4).